2007-0226

OPC Technology Utilized to Automate pH Standardization

For over twenty years the life science industry has utilized in-situ pH electrodes in bioprocess applications. The purpose of these electrodes is to provide continuous measurement of pH in the process. Regrettably, although the design of in-situ pH electrodes has continued to advance, these design changes have not addressed a critical performance issue. That issue being the fact that in bioprocess applications the reference junction of the pH electrode becomes fouled and results in a drifting of the pH measurement. To overcome the challenge of pH drift the life science industry adopted the practice of “pH standardization”. This practice occurs when the pH value indicated by the in-situ pH electrode does not match the pH value of the process sample. In these instances the in-situ pH electrodes value is “standardized” (i.e. changed) to that of the process sample.

In an ongoing effort to optimize the practice of pH standardization the life science industry has constantly sought more capable instruments for analyzing process samples and determining their pH. Early versions of these instruments consisted of benchtop pH analyzers utilizing poorly performing laboratory pH electrodes. These early instruments where labor intensive and could provide only a single process measurement from a given process sample.

As their processes evolved the life science industry became increasingly aware that the design of the benchtop pH analyzer had to evolve as well if they where going to be successful. The result was the introduction of the chemical analyzer and its widespread acceptance in the life science industry. These state of the art devices had three distinct advantages over their predecessors;

1. The engineering of these devices permitted them to compensate for the process environment thereby enabling a more accurate measurement.
2. In addition to pH these devices where able to provide additional process measurements such as glucose, dissolved oxygen, dissolved CO_2 and more than twelve other measurements of interest.
3. These devices introduced the use of on-line samplers to automate the collection of process samples.

While the technology for conducting the pH measurement had advanced so as to better replicate that of the in-situ electrode and the ability to automatically grab a process sample had been successfully introduced, the process of standardization still required at least one operator. The role of this individual was to monitor the in-situ pH electrode for indications of drift, activate the chemical analyzer, evaluate the resulting process measurement and if required then manually standardize the in-situ pH electrode. The result was a labor intensive process that required operator availability 24/7, did not address the potential for operator error in data entry and failed to improve the traceability of the process.

Finesse Solutions, LLC
3350 Scott Blvd, Bldg 1
Santa Clara, CA 95054

9351 Irvine Blvd
Irvine, CA 92618

800-598-9515
www.finesse.com

OPC® FOUNDATION MEMBER

2007-0226

In 2006 the practice of pH standardization in bioprocess applications experienced a dramatic change when open connectivity OPC technology was utilized to integrate the in-situ pH electrode, chemical analyzer and on-line autosampler into an automated process. The driving force behind this automation was an industry leading manufacturer whose desire it was to implement a validateable automated pH standardization process that could be left unattended while delivering reduced process costs and improved process quality in a compliant electronic notebook format.

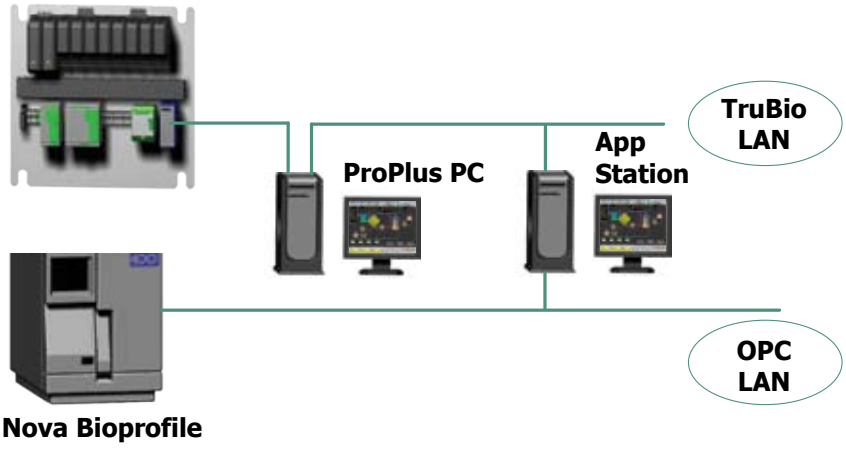
To consider this undertaking a success it was decided at the outset that three critical milestones had to be successfully met:

First, the resulting system would have to be fully automated and thus able to operate unattended. This unattended operation would include the ability of the system to identify from which bioreactor the sample had been taken, when the sample was analyzed and when the associated value was transmitted to the controller. All of which had to be placed automatically on the continuous historian of the bioreactor controller and able to be generated from there as an electronic report.

Second, the bioreactor controller would be able to compare the pH measurement from the in-situ pH electrode and the pH measurement from the chemical analyzer on a fully configurable scheduled basis. Only if the difference between the two was outside the user definable limits would standardization be permitted to occur.

Third, that if either the in-situ pH electrode or chemical analyzer gave an indication of catastrophic failure the bioreactor controller would notify an operator immediately via phone and/or e-mail and place the system in a user defined “standby” mode.

The equipment used in this automation of pH standardization included a TruLogic Controller enabled by the TruBio OS from Finesse and a Nova Biomedical Bioprofile 400 chemical analyzer complete with an on-line autosampler. The network topology involved the use of OPC technology to interface the chemical analyzer to the bioreactor controller (Fig 1 below).



OPC Network Topology for Nova Bioprofile

Finesse Solutions, LLC
3350 Scott Blvd, Bldg 1
Santa Clara, CA 95054

9351 Irvine Blvd
Irvine, CA 92618

800-598-9515
www.finesse.com

OPC® FOUNDATION MEMBER

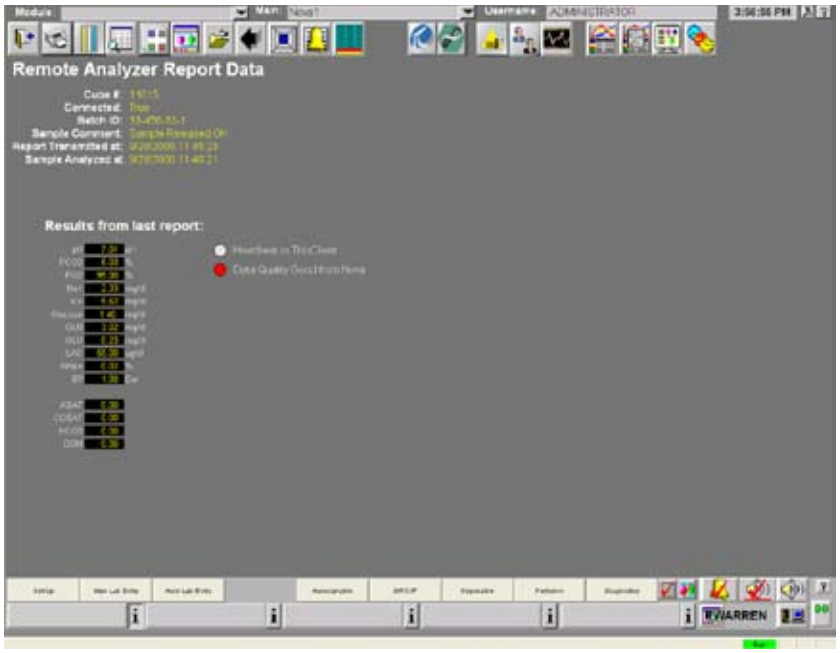
2007-0226

To achieve the first milestone OPC technology was implemented. OPC (Openness, Productivity and Collaboration) technology was first introduced in process control applications in the late 1990's with the stated goal of developing a standard for accessing real time data in Windows operating systems. In practice OPC utilizes a Client/Server topology and requires a single Ethernet cable. The use of OPC enabled the Nova Biomedical chemical analyzer to simultaneously transmit the pH measurement as well as the sample identification and time/date stamp to the TruLogic bioreactor controller. Once at the controller the transmitted values where placed on the embedded continuous historian and a report generated.

The second milestone was achieved by utilizing the embedded Recipe Builder functionality in the TruBio OS. This allowed the pH measurement being supplied by the Nova Biomedical chemical analyzer to be compared to the pH measurement being supplied by the in-situ pH electrode on a configurable scheduled basis. Additionally, it allowed for the two values to be compared based on user defined allowable limits and for the TruLogic bioreactor controller to initiate pH standardization only if those limits where exceeded.

The third and final milestone was achieved through the use of the embedded TruHealth functionality in the TruBio OS. This allowed for the real time monitoring of sensor diagnostics from the in-situ pH electrode and diagnostics from the Nova Biomedical chemical analyzer to permit both indication and operator notification of catastrophic failure.

The interface between the Nova Biomedical chemical analyzer and TruLogic bioreactor controller was implemented in the following form (Fig 2 below)



Automated Data Entry

To learn more about this solution for automating pH standardization or to inquire about other process solutions from Finesse please give us a call at (800) 598-9515 or visit us on the web at www.finesse.com

Finesse Solutions, LLC
3350 Scott Blvd, Bldg 1
Santa Clara, CA 95054

9351 Irvine Blvd
Irvine, CA 92618

800-598-9515
www.finesse.com

OPC® FOUNDATION MEMBER